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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,752	09/18/2003	Tran Thong	117163.00088	8009

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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/23/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/23/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/666,752	THONG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 27, 2006 has been entered. Claims 3-4, 6-26 and 33-42 are cancelled. Claims 1-2, 5 and 27-32 are pending.

Specification

2. The Examiner has accepted the new title, submitted on December 27, 2006.

Claim Objections

3. Claims 28, 30 and 32 are objected to because of the following informalities: there appears to exist a typographical error in the dependencies of these claims. Currently, Claim 28 is listed in the Application as being dependent from Claim 4, however Claim 4 has been deleted. Appropriate correction is required.

4. Applicant is advised that should claims 27, 29 and 31 be found allowable, claims 28, 30 and 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the

same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102/35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5 and 27-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Starkweather (U.S. 5,836,971). As to Claim 1, Starkweather discloses an implantable cardioverter/defibrillator/pacemaker (ICD), read as an arrangement 20 for treatment of rhythm disturbances, especially tachycardia and fibrillation of a heart 28 (see Starkweather Fig. 1, Abstract and column 1, lines 7-16 and 32-39) comprising a sense amplifier 42 coupled to a control/timing circuit 22, collectively read as a device for detecting the heart rhythm (i.e. the time that elapses between consecutive R-waves and/or P-waves) and determining when the lower limit of a fibrillation rate zone is exceeded, read as determining when a fibrillation threshold limit is exceeded, where the fibrillation threshold limit corresponds to a first predetermined heart rate value (see (Starkweather Fig. 3, column 7, lines 43-59, column 8, lines 22-42 and column 9, lines 3-44). The arrangement 20 of Starkweather further comprises a high voltage generator 26 and pulse generator 24, collectively read as a therapy delivery device, connected to the heart rhythm detecting device (sense amplifier 42 and control/timing circuit 22) to begin to treat a fibrillation episode when the fibrillation threshold

limit is exceeded (see Starkweather Fig. 1, column 7, lines 20-22, column 9, lines 55-67, column 10, lines 1-5, column 13, lines 64-67 and column 14, lines 1-4).

Starkweather further discloses that the fibrillation threshold limit is lowered, i.e. a rate zone below the current rate zone the heart rhythm has been classified into is "pulled up" into the current rate zone for redetection purposes to ensure that the patient will receive optimal therapy upon subsequent arrhythmia redetections, i.e. the therapy delivery device continues to treat the same arrhythmia episode as long as the heart rhythm detecting device determines that the heart rate still exceeds the now "pulled up" lower limit of the rate zone, read as a redetection threshold limit (see Starkweather column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47). Starkweather specifies at column 6, lines 52-60 that

> Typically, an arrhythmia is considered to be a rapid irregular rhythm of the heart, e.g., ventricular tachycardia or ventricular fibrillation. However, for purposes of the present application the term arrhythmia also includes atrial tachycardia, atrial fibrillation, and asystole (a stopped heart). Thus, as used herein, the term "arrhythmia" is used broadly to indicate any irregular rhythm of the heart that interferes with the heart's ability to perform its basic function as a pump.

Starkweather also discloses that there are the following rate zones for the detected arrhythmias: fibrillation, high rate tachycardia and low rate tachycardia (see Starkweather Fig. 3). Starkweather expressly discloses the process for detection, treatment and redetection of a high rate ventricular tachycardia (VT) and generally discloses the process carried out by the arrangement 20 for detection, treatment and redetection of an arrhythmia in the other rate zones (i.e. low rate tachycardia or fibrillation). Although Starkweather does not expressly disclose the method for when the detected arrhythmia falls into the other rate zones disclosed, it is inherent that when the detected arrhythmia is a fibrillation, by default a synonymous method would occur upon detection of an arrhythmia in the fibrillation rate zone meaning (again by default) that a fibrillation is detected when the detected heart rate exceeds a fibrillation threshold limit of

approximately 240 bpm. After delivering of defibrillation shocks, the redetected heart rhythm is then compared to a redetection threshold limit of 200 bpm (the "pulled up" lower limit of the high rate VT rate zone into the current rate zone) and the therapy delivery device continues to treat the same fibrillation episode if the detected heart rhythm exceeds 200 bpm (i.e. the redetection threshold limit which is lower than the fibrillation threshold limit of 240 bpm and higher than a tachycardia threshold limit of approximately 150 bpm (see Starkweather Figs. 3 and 4A-4D, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

Starkweather also specifies that the sense amplifier 42 coupled to a control/timing circuit 22, collectively read as a device for detecting the heart rhythm can detect an arrhythmia by monitoring atrial intervals instead of ventricular intervals *if so desired* (see Starkweather column 8, lines 37-42 and column 9, lines 3-14) [emphasis added]. Starkweather expressly discloses the process for detection, treatment and redetection of arrhythmias occurring in the ventricles, as previously discussed, and generally discloses that the arrangement 20 for treatment of rhythm disturbances occurring in the atria. It is inherent, or at least obvious to one having ordinary skill in the art, that a synonymous method that is used by the arrangement 20 to detect, treat and redetect arrhythmias that occur in the ventricles would be and is applied to those arrhythmias that occur in the atria in order to provide tired therapy that dynamically readjusts boundaries between rate zones so as to ensure that increasing tiers of therapy are delivered from one redetection to the next in a timely matter for all types of rhythm disturbances that may occur in all chambers of the heart 28 (see Starkweather column 4, lines 7-67, column 5, lines 1-59, column 6, lines 45-65, column 7, lines 4-59, column 8, lines 21-58 and column 9, lines 3-14).

7. As to Claim 2, Starkweather discloses that the therapy deliver device delivers a series of electrical impulses to the heart 28 via electrodes 32, 38 and 40 (see Starkweather column 7, lines 20-32, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

8. As to Claim 5, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may comprise an electrode 32 that may be situated in a region of an atrium of the heart 28 to detect the electrical activity thereof and that the therapy device including a pulse generator 24 and high voltage generator 26 may be connected to electrode 32 to deliver electrical pulses (an anti-tachycardia pacing regimen for example) to the atrium (see Starkweather column 7, lines 1-19).

9. As to Claims 27-30, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may determine when a tachycardia is occurring and the therapy device begins to treat the tachycardia when the tachycardia is detected, i.e. the detected heart rhythm is less than the lower limit for a high rate tachycardia but greater than the lower limit for a low rate tachycardia and pulse generator 24 emits an anti-tachycardia pacing regimen or the detected heart rhythm is less than the lower limit for fibrillation but greater than the lower limit for high rate tachycardia and the therapy delivery device delivers a first programmed shock for the VT high rate zone (see Starkweather Fig. 3 column 7, lines 20-32, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

10. As to Claims 31-32, Starkweather discloses that "pulling up" all lower rate zones into the corresponding rate zone permits the arrangement 20 to ensure that all subsequent arrhythmia redetection in a lower rate zone does not result in the delivery of a lower tier of therapy, e.g. a

lower energy shock than the last tier of therapy delivered (see Starkweather column 13, lines 64-67 and column 14, lines 1-23). By default, the arrangement 20 of Starkweather is designed so that no tachycardia treatment (i.e. cardioversion shocks) is performed during a fibrillation treatment (i.e. high every defibrillation shocks).

Response to Arguments

11. Applicant's arguments filed December 27, 2006 have been fully considered but they are not persuasive. In response to Applicant's argument that "Starkweather does not teach *or suggest* a heart rhythm detecting device determining whether an atrial redetection threshold limit, corresponding to a second predetermined heart rate value, is still exceeded immediately after the therapy device has treated the atrial fibrillation episode, the atrial redetection threshold limit being lower than the atrial fibrillation threshold limit and higher than a tachycardia threshold limit which corresponds to a third predetermined heart rate value (see page 7 of the Remarks), the Examiner respectfully disagrees. As discussed above, the Examiner has noted that Starkweather *expressly discloses* the process for detection, treatment and redetection of a high rate ventricular tachycardia (VT) [emphasis added]. Starkweather, however, does *generally disclose* the process carried out by the arrangement 20 for detection, treatment and redetection of an arrhythmia in the other rate zones (see Starkweather Fig. 3, column 6, lines 52-67 and columns 7-14) [emphasis added]. Although Starkweather does not expressly disclose the method for when the detected arrhythmia falls into the other rate zones disclosed it is inherent that when the detected arrhythmia is a fibrillation, by default a synonymous method would occur upon detection of an arrhythmia in the fibrillation rate zone.

Starkweather expressly discloses at column 6, lines 45-65 that the description "is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention" and that the device may detect and treat atrial arrhythmias *if so desired* [emphasis added]. It is inherent, or at least obvious to one having ordinary skill in the art, that a synonymous method that is used by the arrangement 20 to detect, treat and redetect arrhythmias that occur in the ventricles would be and is applied to those arrhythmias that occur in the atria in order to provide tired therapy that dynamically readjusts boundaries between rate zones so as to ensure that increasing tiers of therapy are delivered from one redetection to the next in a timely matter for all types of rhythm disturbances that may occur in all chambers of the heart 28 (see Starkweather column 4, lines 7-67, column 5, lines 1-59, column 6, lines 45-65, column 7, lines 4-59, column 8, lines 21-58 and column 9, lines 3-14). Treating atrial fibrillation, atrial tachycardia and/or atrial flutter using "tired therapy" is well known and conventional in the art of implantable medical devices with both Alt (U.S. 5,403,355) and Alt (U.S. 5,458,622) being examples.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel
Examiner
Art Unit 3766

01/12/07

Robert E. Pezzuto
Supervisory Patent Examiner
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